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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,297	06/23/2003	Jacob Stoltze	S63.2-11064-US01	3241

490 7590 08/18/2006

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,297

Applicant(s)

STOLTZE ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/17/03, 10/20/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 10/17/03 and 10/20/03 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12 and 25 recite the matrix being non-elastomeric and the fibers being elastomeric. However, there is no teaching in the specification for said limitation. Therefore, there is a lack of written description to allow one of ordinary skill in the art to make or use the invention as recited.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Applicant is required to clarify to what the claim is intended to be drawn to, i.e., either the catheter alone or the combination of the catheter and the stent. The Applicant sets forth the combination of the catheter and the stent in claim 27 when describing the a portion of the stent is releasably attached to the inflatable portion of the catheter, which is inconsistent with preamble of the independent claim 14, which sets forth the subcombination of a catheter. Applicant is required to make the language of the claims consistent with the intent of the claims. It should also be noted that in considering the claims on the merits, the Examiner will consider the claims as drawn to the combination.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 6-11, 14, 16-18 and 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,201,706 to Noguchi et al.

Noguchi teaches a dilation balloon catheter comprising fibers **12** in a matrix material **10,12**, wherein the fibers are reinforcement fibers that control expansion, wherein the fibers are embedded between the matrix layers; wherein the fibers are braided or wound in a cylindrical shape (col. 3, lines 55-58); wherein the fiber is made of

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a polyethylene fibers (col. 4, line 2), which are thermoplastic and non-elastomeric; wherein the matrix is an elastomeric material comprising polyurethane (col. 3, line 42); wherein the catheter comprises a first end and a second end, wherein the first end comprises the inflatable balloon, wherein a lumen extends from the inflatable balloon to the second end (seen in Fig. 5).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noguchi et al. and in view of UK 1,566,674 to Hanecka et al.

Noguchi teaches a fabric fiber body but is silent with regards to the orientation of the fabric body having a helical pattern. However, Hanecka teaches a similar reinforced balloon catheter having a fabric body formed with a helical pattern (page 2, line 117).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to modify the fabric fiber body of Noguchi to include a helical pattern because it would allow the inflatable balloon to expand to a predetermined size that is determined or controlled by said helical pattern.

11. Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noguchi et al.

Noguchi is silent with regards to a non-elastic layer **10,12** and an elastic body **12**. However, Noguchi teaches the recited polymers in the claims, which are capable of having the same characteristics recited in the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the layers **10,12** to be non-elastic and the fiber body to be elastic since Noguchi teaches identical materials that are capable of having the same characteristics. It would also be a mere design choice to make the layers **10, 12** be non-elastic and the fiber body be elastic since the Applicant has not disclosed that having non-elastic layers **10, 12** or an elastic body **12** solves any stated problems or is for any particular purpose and it appears that the invention would perform equally well with the reversal of parts taught by Noguchi.

12. Claims 13, 15, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noguchi et al. and in view of US 5,100,429 to Sinofsky.

Noguchi teaches an inflatable balloon catheter that is capable of expanding a stent but is silent with regards to the combination of the catheter and the stent. However, Sinofsky teaches a stent **112** releasably attached or mounted by a bond (col. 9, lines 51-53) to an inflatable portion of a catheter **120**, wherein the stent is capable of

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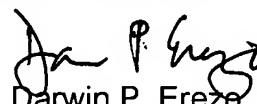
retaining a deployed configuration. Therefore, it would have been obvious to one of ordinary skill in the art to use a stent with the inflatable balloon of Noguchi because the reinforced inflatable balloon of Noguchi would allow the use of high-pressure within the balloon to fully inflate the balloon without rupturing said balloon.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Darwin P. Erezzo
Examiner
Art Unit 3731

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